



NATIONAL MISSION ON IMMUNISATION

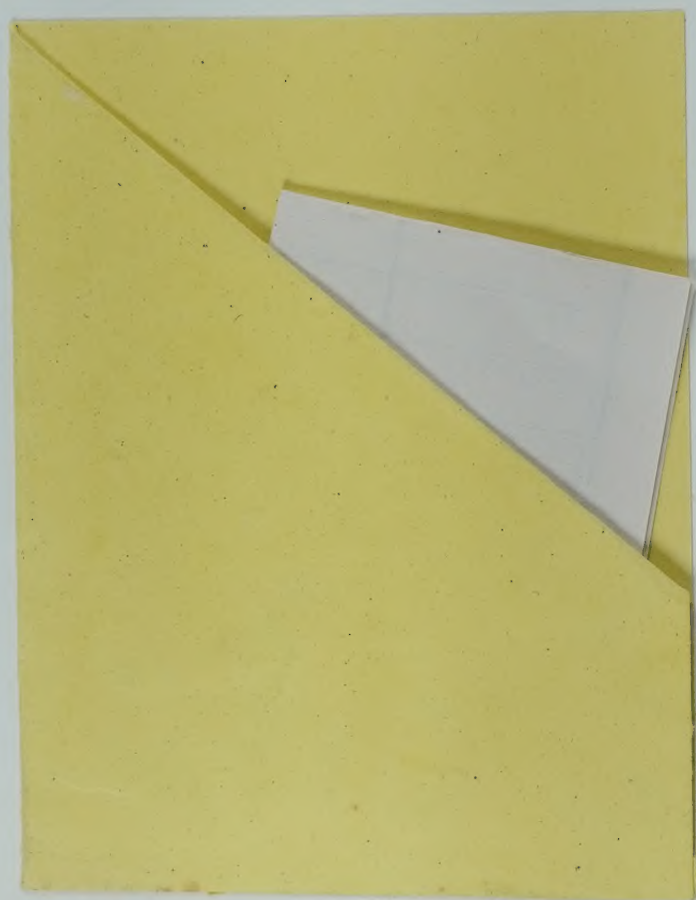


सत्यमेव जयते

1988

DEPARTMENT OF FAMILY WELFARE
MINISTRY OF HEALTH AND FAMILY WELFARE
GOVERNMENT OF INDIA
NEW DELHI

DEPARTMENT OF BIOTECHNOLOGY
MINISTRY OF SCIENCE AND TECHNOLOGY
GOVERNMENT OF INDIA
NEW DELHI



NATIONAL MISSION ON IMMUNISATION

CONFIDENTIAL HEALTH CARE
ALL INFORMATION IS KEPT
Private - 1000000

NATIONAL MISSION ON IMMUNIZATION

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COMMUNITY HEALTH CELL
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FOREWORD

The Universal Immunization Programme, an effective intervention to prevent mortality and morbidity of children and mortality of pregnant women, was launched on the 19th November, 1985 as a "Living Memorial" to the memory of our late Prime Minister, Smt. Indira Gandhi. The Programme made a modest beginning by covering 30 districts in the country and catchment areas of 50 Medical Colleges. The Programme is being extended in phases and, at present, we are covering 182 districts and catchment areas of all the 106 Medical Colleges. We hope to cover the entire country by 1990. Having realised the tremendous impact this Programme can have on the health status of the pregnant women and children of this country, and the need for comprising the time frame without losing the impact, the Government had decided to have a "Technology Mission on Vaccination and Immunization of Vulnerable Population Specially Children."

2. Broadly, the objectives of the Mission are to reduce morbidity and mortality due to the six vaccine-preventable diseases, reduce mortality of pregnant women due to Tetanus and to achieve self-sufficiency in vaccine production. Under the umbrella of the Mission, all aspects connected with the delivery of services, research and development on improved and new vaccines, are also intended to be covered.

3. The Mission has been divided into two parts, viz., Part-I, dealing with implementation of the Programme and, the Part-II, dealing with the research and development of vaccines. The first part is being implemented by the Ministry of Health and Family Welfare and, the second part by the Department of Bio-Technology. The Ministry of Health and Family Welfare is charged with the nodal responsibility for this Mission.

4. This booklet on the "Technology Mission on Vaccination and Immunization of Vulnerable Population Specially Children" is intended to give brief information on the components of the Mission and this will form the basis for detailed write-ups on each component, later.

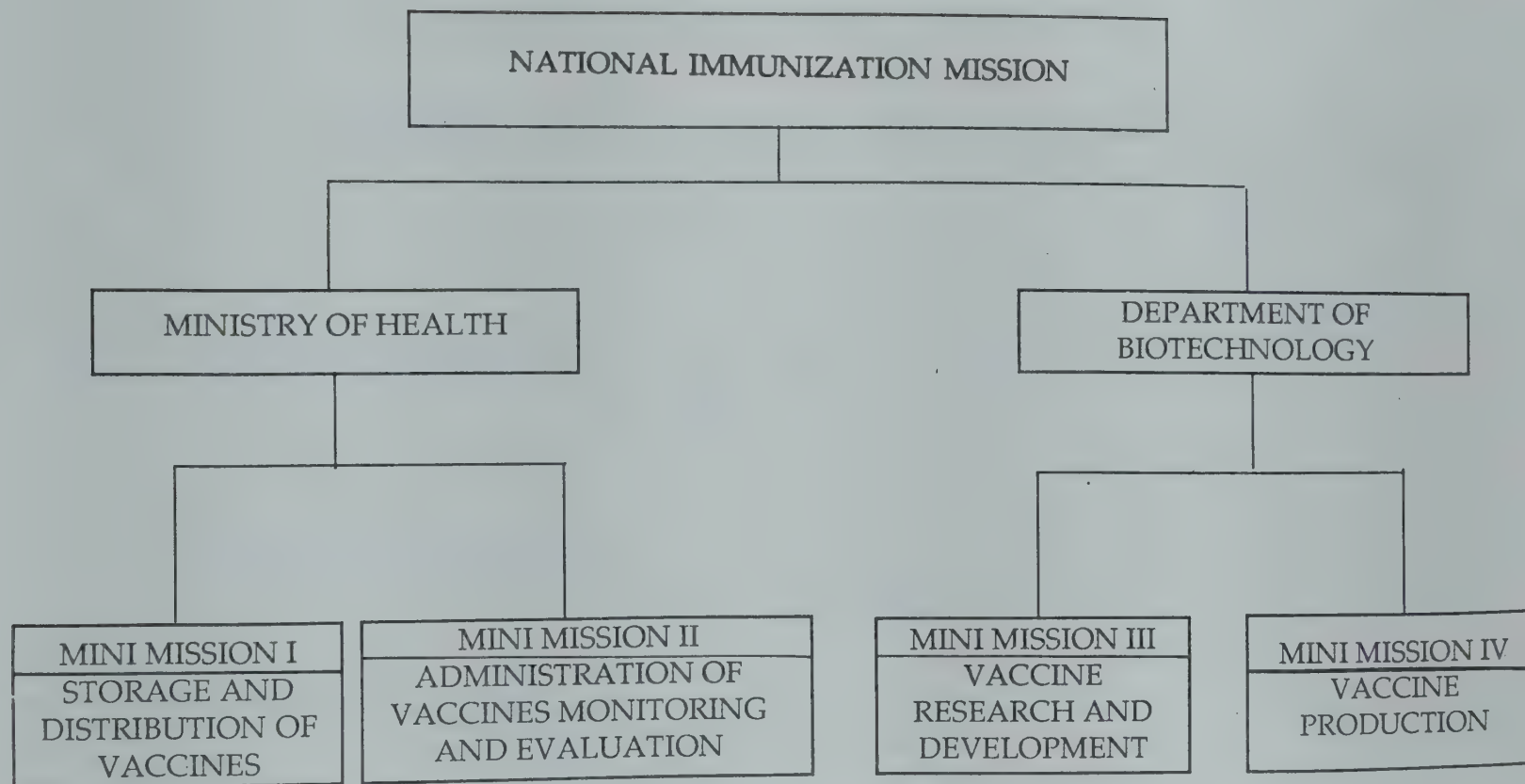
NEW DELHI: 1st September, 1987

Sd / -
(P.K. UMASHANKAR)
Special Secretary

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I. NATIONAL MISSION ON IMMUNIZATION



OBJECTIVES OF THE IMMUNIZATION MISSION

- * Reduce morbidity and mortality due to Diphtheria, Pertussis, Tetanus, Poliomyelitis, Tuberculosis, Measles among infants
- * Reduce mortality due to Tetanus amongst pregnant women
- * Achieve self-sufficiency in vaccine production

II. MINI MISSION I STORAGE AND DISTRIBUTION
OF VACCINES

MINI MISSION II ADMINISTRATION OF VACCINES,
MONITORING AND EVALUATION

METHODOLOGY

- * Ensure supply of full requirement of vaccine
- * Ensure supply of required equipment i.e. needles, syringes, sterilization equipment
- * Ensure proper transportation and storage of vaccine at ambient temperatures
- * Strengthen infrastructure at field level
- * Train staff in adequate numbers
- * Closely monitor quality of vaccination
- * Encourage quick indigenisation of cold chain equipment
- * Achieve self-reliance in vaccine production
- * Establish system for concurrent evaluation/independent evaluation
- * Involve voluntary agencies in enumeration and actual vaccination
- * Promote community mobilization
- * Develop effective information education & communication method
- * Develop facilities for regular field testing of vaccines
- * Adopt phased district-wise approach to implementation with special focus in problem areas (U.P., Rajasthan, M.P., Bihar, Orissa)
- * Coordinate immunization programme with ICDS

COVERAGE

- * 100% of pregnant women with T.T. by 1990
- * 85% of infants (0-12 months) with DPT, Polio, BCG & Measles by 1990**

Volume of Work (in lakhs)

	1985-1990
Pregnant Women	925
Infants (85%)	822
Contacts	6000
Vaccine (Doses)	9900
Injections	6000

- *** 85% of coverage of infants is done taking into account herd community.

YEAR-WISE PROPOSED NUMBER OF BENEFICIARIES

1985-86 to 1989-90

(Figures in Millions)

Universal Immunization Programme Target

Year	Infants	Pregnant Women
1985-86	1.44	1.63
1986-87	4.61	6.10
1987-88	9.32	11.98
1988-89	13.82	17.74
1989-90	19.27	25.28

III. BASIC INFORMATION

ESTIMATED INFANT DEATHS IN ONE YEAR : 20 LAKHS

- * Nearly 15% (3.5 lakhs) die of neo-natal Tetanus
- * About 1.7 lakhs children get paralytic Polio
- * Almost every infant is prone to get Measles and Pertussis which can have many adverse effects

CAUSES OF DEATH STATISTICS

Percentage Distribution of Specific Causes Belonging to the Group "Diseases Peculiar to Infancy"
India (Rural): 1979-1983

Sl. No.	Specific cases under diseases peculiar to infancy	Percentage of Deaths			
		1979	1980	1981	1983
1	2	3	4	5	6
1.	Prematurity	31.4	33.5	36.2	43.6
2.	Respiratory infection of new born	16.3	17.5	15.5	13.7
3.	Malnutrition	13.1	11.3	11.7	1.8
4.	Diarrhoea of new born	10.8	9.4	10.0	9.5
5.	Convulsions	8.3	6.1	7.0	0.7
6.	Others	20.1	22.3	19.6	30.7
Total		100.0	100.0	100.0	100.0
No. of deaths under the group 'Diseases Peculiar to Infancy'		2,280	2,409	2,112	1,898

Source: Registrar General, India-Model Registration Scheme, Survey of Causes of Death (Rural) 1983 - A Report.

CAUSES OF DEATH STATISTICS

Percentage of Deaths by Causes Related to Child Birth and Pregnancy Maternal Deaths
India (Rural): 1979-1983

Specific Causes	1979	1980	1981	1982	1983
1	2	3	4	5	6
Abortion	11.7	12.5	13.7	10.1	10.7
Toxaemia	16.1	12.4	8.0	12.5	12.1
Anaemia	15.0	15.8	17.7	24.4	18.9
Bleeding of pregnancy and puerperium	20.0	15.8	23.4	26.2	23.8
Malposition of child leading to death of mother	10.5	13.4	9.2	7.2	8.3
Puerperium sepsis	11.7	12.4	13.1	8.3	11.6
Not classifiable, specify symptoms	15.0	17.7	14.9	11.3	14.6
Total	100.0	100.0	100.0	100.0	100.0
Sample No. of deaths	180	209	175	168	206
Percent to total deaths	1.1	1.2	1.0	1.0	1.2

Source: Model Registration Scheme - Survey of causes of death (Rural) 1983 - A Report Registrar General, India.

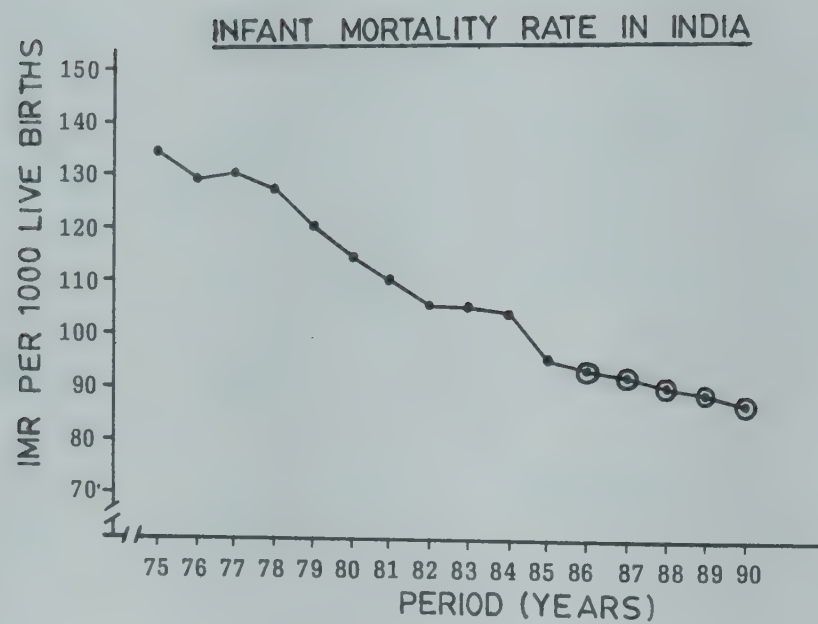
DEMOGRAPHIC ESTIMATES 1985

Population	7458 Lakhs
Birth Rate	32.7 Per Thousand
Death Rate	11.7 Per Thousand
Infant Mortality Rate	95 Per Thousand
No. of Pregnant Women	258 Lakhs
No. of Infants	245 Lakhs

GOALS FOR MOTHER AND CHILD CARE

Indicator	Current Level	Goals		
		1985	1990	2000
Infant Mortality (thousand live births)	125 (1978)	106	87	Below 60
Pre-natal Mortality (thousand live births)	67 (1976)	--	--	Below 30-35
Pre-School Child (1-5 years) Mortality	24 (1976)	20-24	15-20	10
Maternal Mortality Rate	4-5 (1976)	3-4	2-3	Below 2
Pregnant Mothers Receiving Ante-Natal Care (%)	40-50	50-60	60-75	100

(Source: National Health Policy Document)



INFANT MORTALITY BY RURAL/URBAN INDIA
AND MAJOR STATES, 1985

(Provisional)

India/States	Rural	Urban	Total
Andhra Pradesh	90	58	83
Assam	112	91	111
Bihar	109	59	105
Gujarat	112	64	98
Haryana	92	58	85
Himachal Pradesh	87	32	84
Jammu & Kashmir	94	44	86
Karnataka	80	41	71
Kerala	32	30	32
Madhya Pradesh	131	78	122

contd...

India/States	Rural	Urban	Total
Maharashtra	78	49	68
Orissa	135	78	122
West Bengal	85	48	77
Punjab	77	51	71
Rajasthan	114	72	108
Tamil Nadu	93	53	80
Uttar Pradesh	152	77	140
INDIA	105	57	95

INTERVENTIONS TO REDUCE INFANT MORTALITY RATE

- * Antenatal Care - Perinatal Care
- * Immunization
- * Breast Feeding and Infant Nutrition
- * Safe Drinking Water and Better Sanitation
- * Improved Rural Health Care
- * Control of Diarrhoea and ORT
- * Family Planning :
 - Higher Age at First Pregnancy
 - Spacing of Children
 - Small Family Norm
- * Health Education and Female Literacy

EPI TARGET DISEASES

1.	Disease	NEONATAL TETANUS	TETANUS
2.	Causative Agent	Clostridium Tetani	Clostridium Tetani
3.	Mode of Transmission	Broken Skin	Broken Skin
4.	Incubation Period	3 - 14 days	10 - 15 days
5.	Major Signs and Symptoms	* A week later inability to suck and fits worsened by noise or movement, sucks well at birth	* Lockjaw - unable to open mouth fully * Painful contraction of muscles of neck and trunk, bending body like a bow
6.	Complications	--	--
7.	Specific Treatment	Available	Available
8.	Immunity	No	No

EPI TARGET DISEASES

1.	Disease	WHOOPING COUGH
2.	Causative Agent	Bordetella pertussis
3.	Mode of Transmission	Air
4.	Incubation Period	5 - 8 days
5.	Major Signs and Symptoms	<ul style="list-style-type: none">* Fever, cough, cold* coughing paroxysms during 2nd week* bulging eyes, bleeding in eyes during cough spasms* vomiting after cough spasms
6.	Complications	Malnutrition, secondary infections, brain damage
7.	Specific Treatment	Available
8.	Immunity	Yes

EPI TARGET DISEASES

1.	Disease	DIPHTHERIA
2.	Causative Agent	Coryne-bacterium diphtheriae
3.	Mode of Transmission	Air
4.	Incubation Period	2 - 10 days
5.	Major Signs and Symptoms	* Fever * Swollen neck * Membrane in throat * Difficulty in breathing
6.	Complications	Toxins can affect heart muscle and nerves
7.	Specific Treatment	Available
8.	Immunity	Yes

EPI TARGET DISEASES

1.	Disease	MEASLES
2.	Causative Agent	Measles Virus
3.	Mode of Transmission	Air
4.	Incubation Period	9 - 10 days
5.	Major Signs and Symptoms	* Fever * Catarrh * Conjunctivitis * Rash on 3-4th day
6.	Complications	Malnutrition, secondary infections
7.	Specific Treatment	Not available
8.	Immunity	Yes

EPI TARGET DISEASES

1.	Disease	TUBERCULOSIS
2.	Causative Agent	Mycobacterium tuberculosis
3.	Mode of Transmission	Air
4.	Incubation Period	Not known
5.	Major Signs and Symptoms	* Fever * Listlessness * Loss of weight * Coughing * Severe headaches, stiffness of neck and convulsions (Tuberculosis meningitis)
6.	Complications	--
7.	Specific Treatment	Available
8.	Immunity	Not known

EPI TARGET DISEASES

1.	Disease	POLIOMYELITIES
2.	Causative Agent	Polio Virus I, II & III
3.	Mode of Transmission	Food, Water, Air
4.	Incubation Period	5 - 14 days
5.	Major Signs and Symptoms	* Weakness in the arms or legs * Paralysis flaccid * Pain and tactile sensations normal
6.	Complications	Residual paralysis
7.	Specific Treatment	Not available
8.	Immunity	Type specific

NATIONAL IMMUNIZATION SCHEDULE

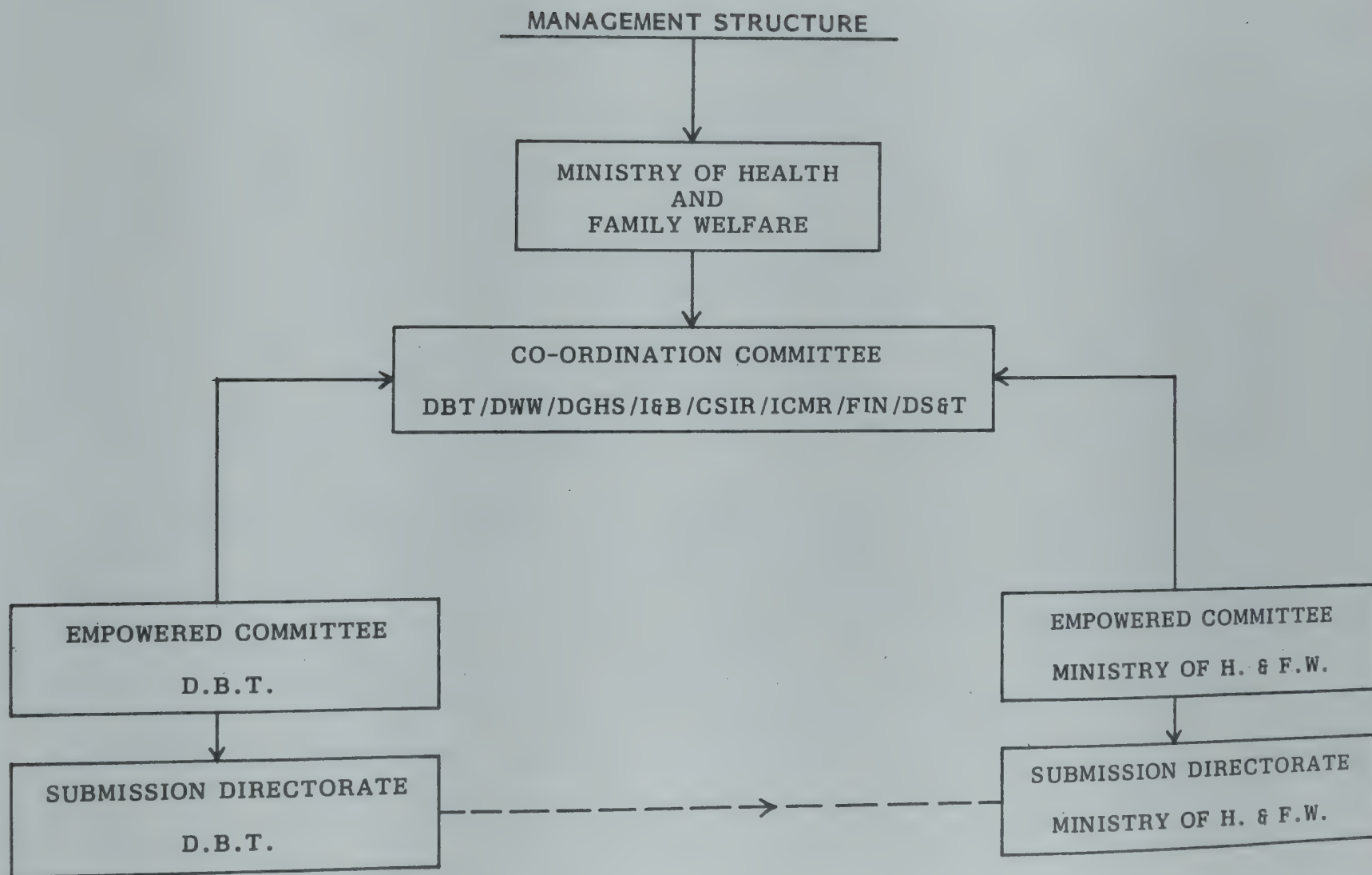
Beneficiaries	Age	Vaccine	No. of Doses	Route of Administration
Infants	— 6 weeks to 9 months	DPT	3	Intra-muscular
	— 6 weeks to 9 months	Polio	3	Oral
	— 6 weeks to 9 months	BCG	1*	Intra-dermal
	— 9 to 12 months	Measles	1	Subcutaneous
* For institutional deliveries BCG should be given at birth.				
Children	— 16 to 24 months	DPT	1	Intra-muscular
	— 16 to 24 months	Polio	1	Oral
Pregnant Women	— 16 to 36 weeks	TT	1**	Intra-muscular

** 2 doses, if not vaccinated previously.

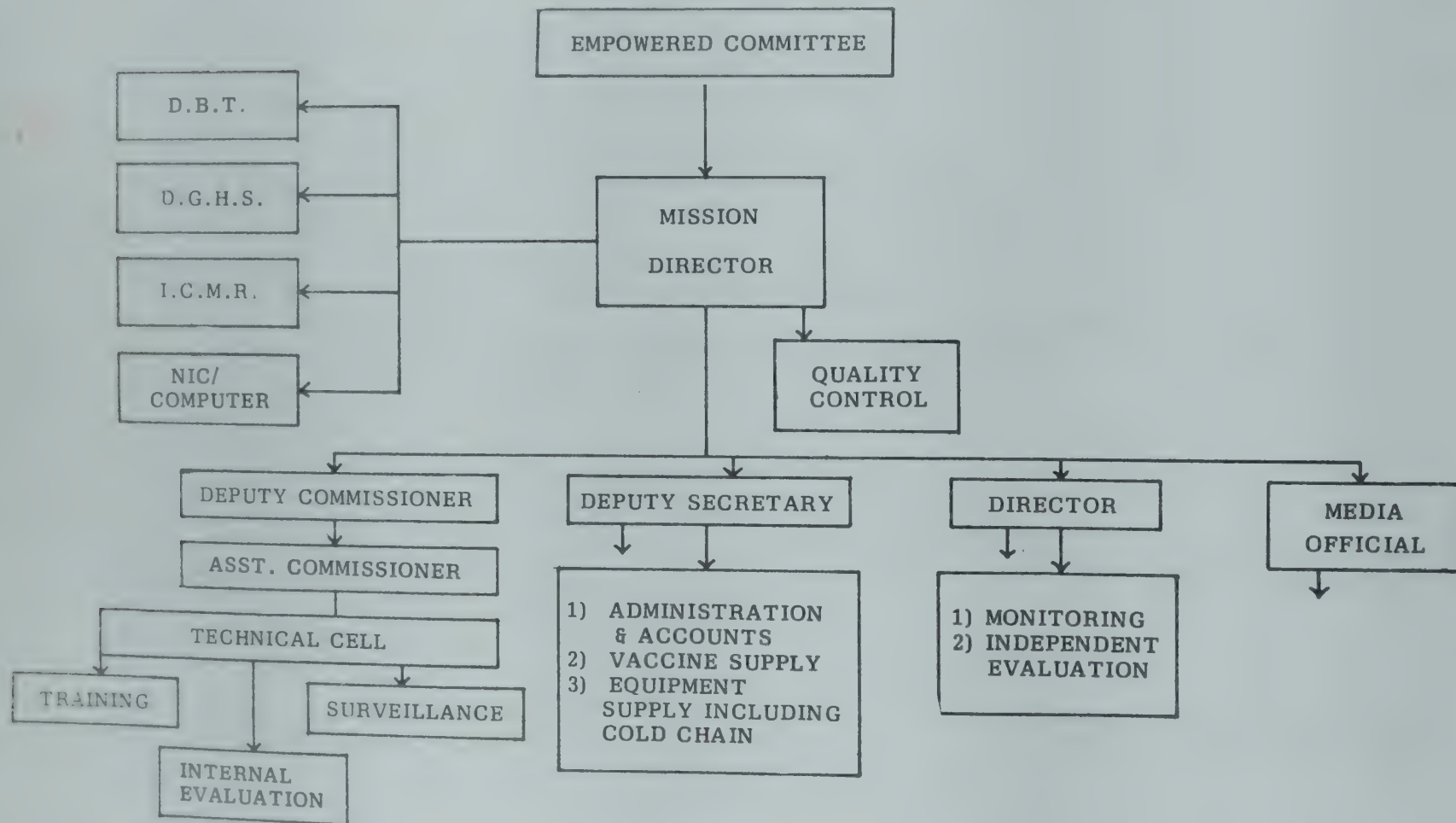
NOTE : Interval between 2 doses should not be less than one month.

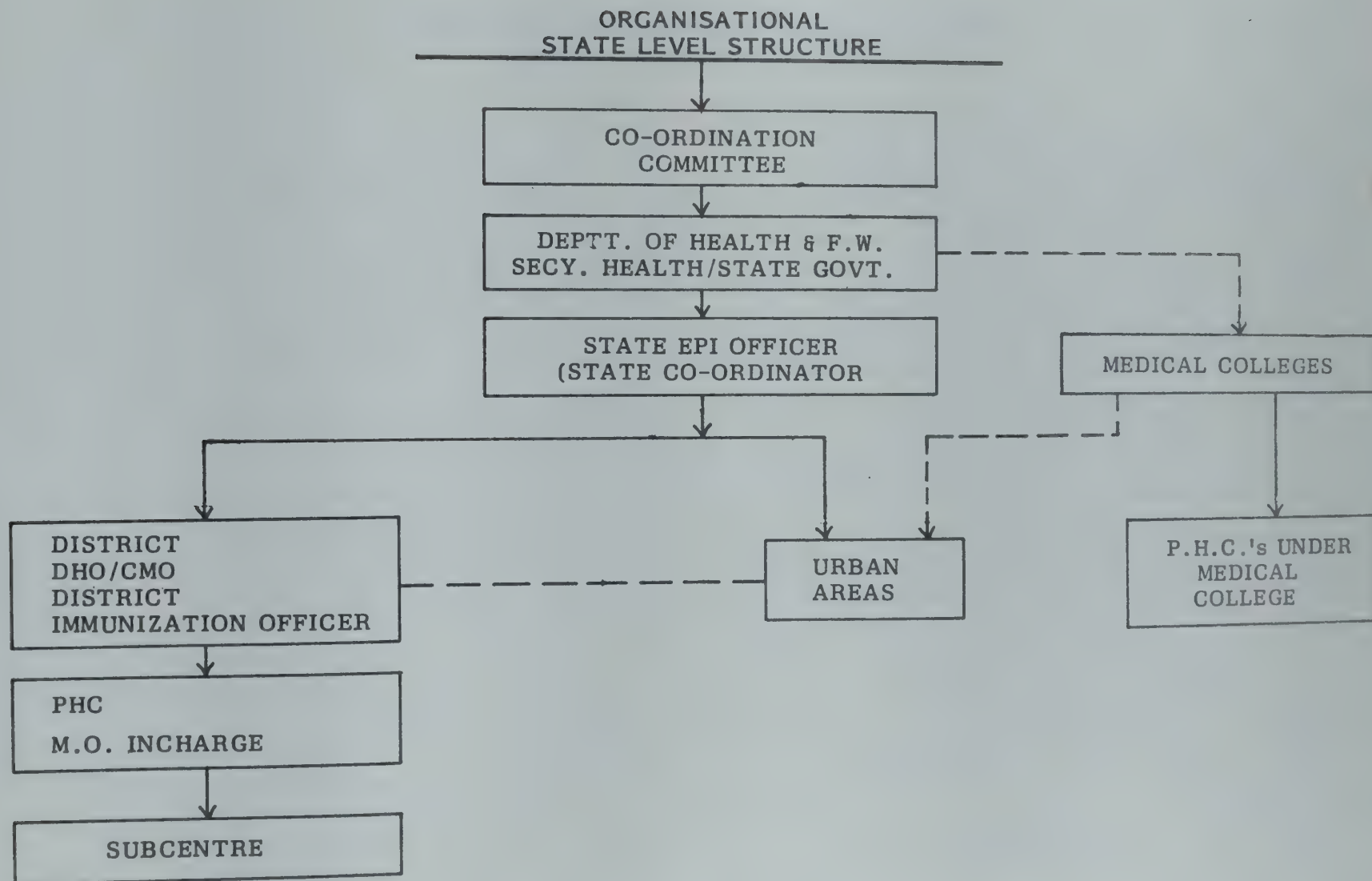
Minor coughs, colds and mild fever are not a contraindication to vaccination.

IV. ORGANISATION

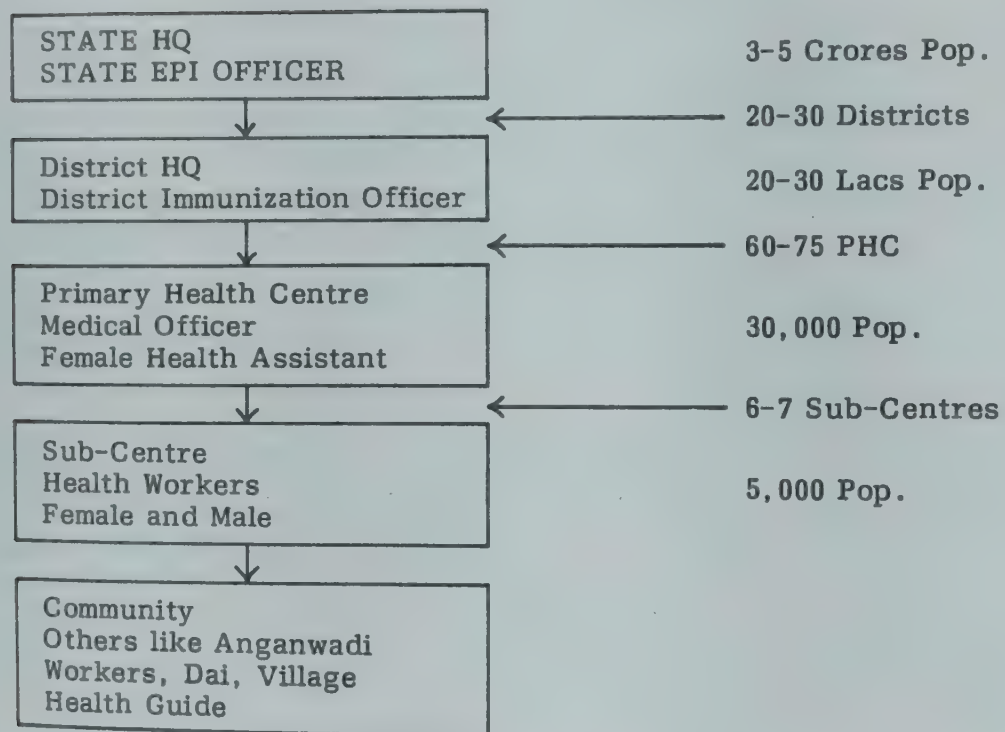


ORG. STRUCTURE - MISSION DIRECTORATE (MINISTRY OF H. & F.W.)

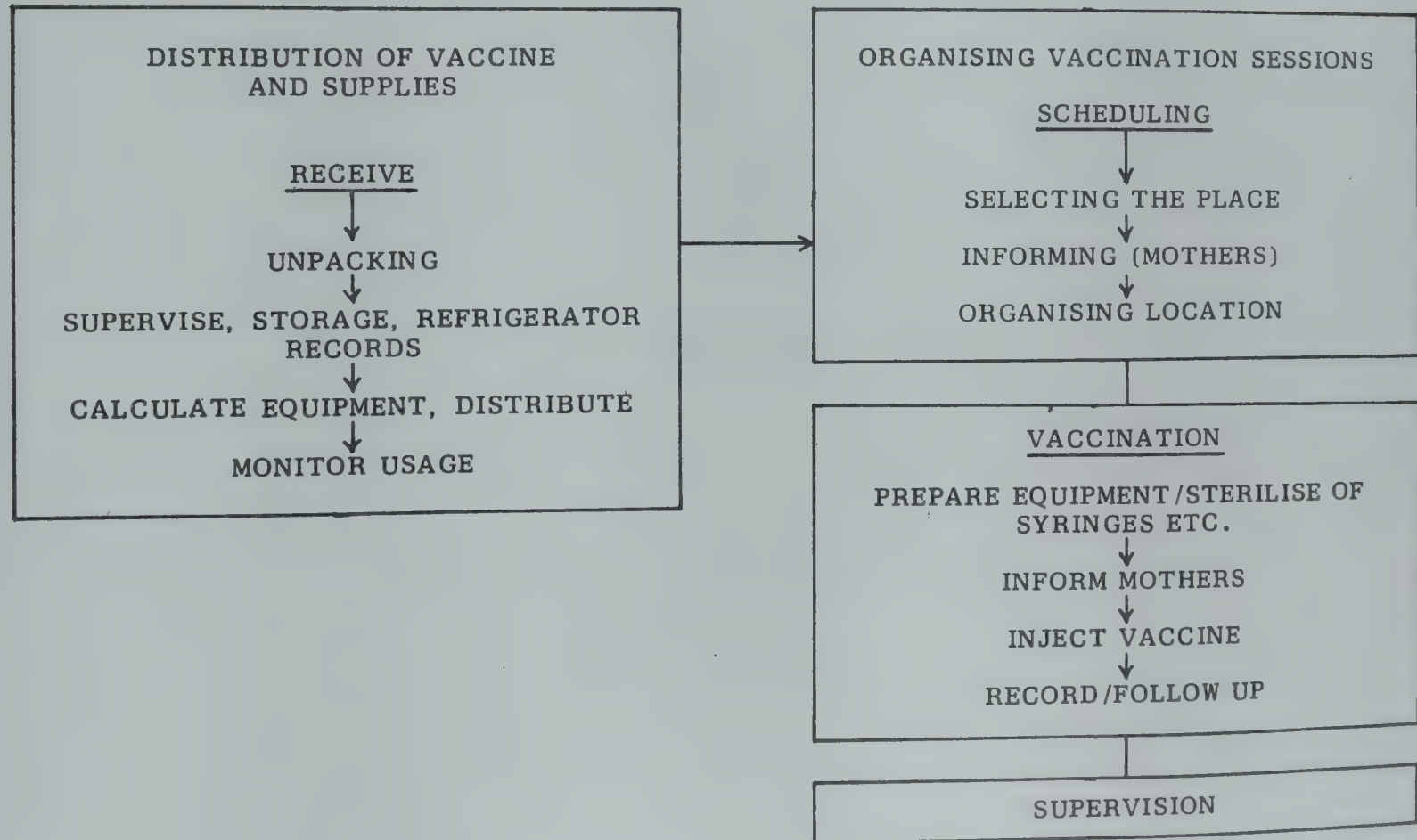




STRUCTURE OF FIELD ORGANISATION (STATE)



IMMUNIZATION IN THE FIELD



V. INFRASTRUCTURE

INFRASTRUCTURE FOR DELIVERY OF SERVICES

Formation	In Operation	To Be Set Up By 1990	Total
Community Health Centre	1,131	1,077	2,208
Primary Health Centre	14,246	9,205	23,451
Sub-Centre	1,01,535	37,983	1,39,518
Post Partum Centre	1,118	636	1,754
Medical Colleges	106	--	106
Hospitals - Government	3,575	--	3,575
Others	3,459	--	3,459
Dispensaries	21,226	--	21,226

VI. VACCINE SUPPLY

VACCINE PRODUCTION AND REQUIREMENT

(In lakhs)

Vaccine	Production Public Sector (Present Capacity)			Production Private Sector (Annual)			Requirement		
	1987-88	1988-89	1989-90	1987-88	1988-89	1989-90	1987-88	1988-89	1989-90
D.P.T.	360	410	450	600	600	800	861	1046	1104
Polio	--	--	10	--	--	--	861	1046	1104
BCG	200	200	200	--	--	--	215	261	276
T.T.	420	450	480	1000	1000	1200	738.40	1150	1171
D.T.	260	260	260	200	200	400	375	379	383
T.A.	74	74	74	--	--	--	376	379	383
Measles		UNICEF	ASSISTANCE				220	313	331

- Note: 1. OPV is produced in HBPCCL, Bombay from imported bulk concentrate
 2. Wastage Factor - 25% for DPT, Polio, TT, DT, TA and BCG
 - 50% for Measles
 3. Private Sector manufacturer of DPT is only Serum Institute of India Ltd, Pune.
 The other private manufacturer, Biological E. will be producing DPT from 1987.

PRODUCTION OF B.C.G. VACCINE (In lakh doses)

S.No.	Institute	Installed Capacity	Produced			Proposed to be produced	
			1984-85	85-86	86-87	1987-88	88-89
1.	BCG Vaccine Laboratory, Guindy, Madras	240.00	165.52	203.87	233.76	200.00	320.00
Total		240.00	165.52	203.87	233.76	200.00	320.00

PRODUCTION OF D.P.T. VACCINE (In lakh doses)

S.No.	Institute	Installed Capacity	Produced			Proposed to be produced	
			1984-85	85-86	86-87	1987-88	88-89
1.	CRI, Kasauli	155.0	112.65	130.88	154.22	160.00	180.00
2.	HBPCL, Bombay	50.00	50.00	60.00	60.00	50.00	70.00
3.	PII, Coonoor	120.00	75.00	92.00	105.00	120.00	135.00
4.	Serum Instt. Pune	--	391.00	342.00	392.00	600.00	600.00
Total:		325.00	628.65	624.88	711.22	930.00	985.00

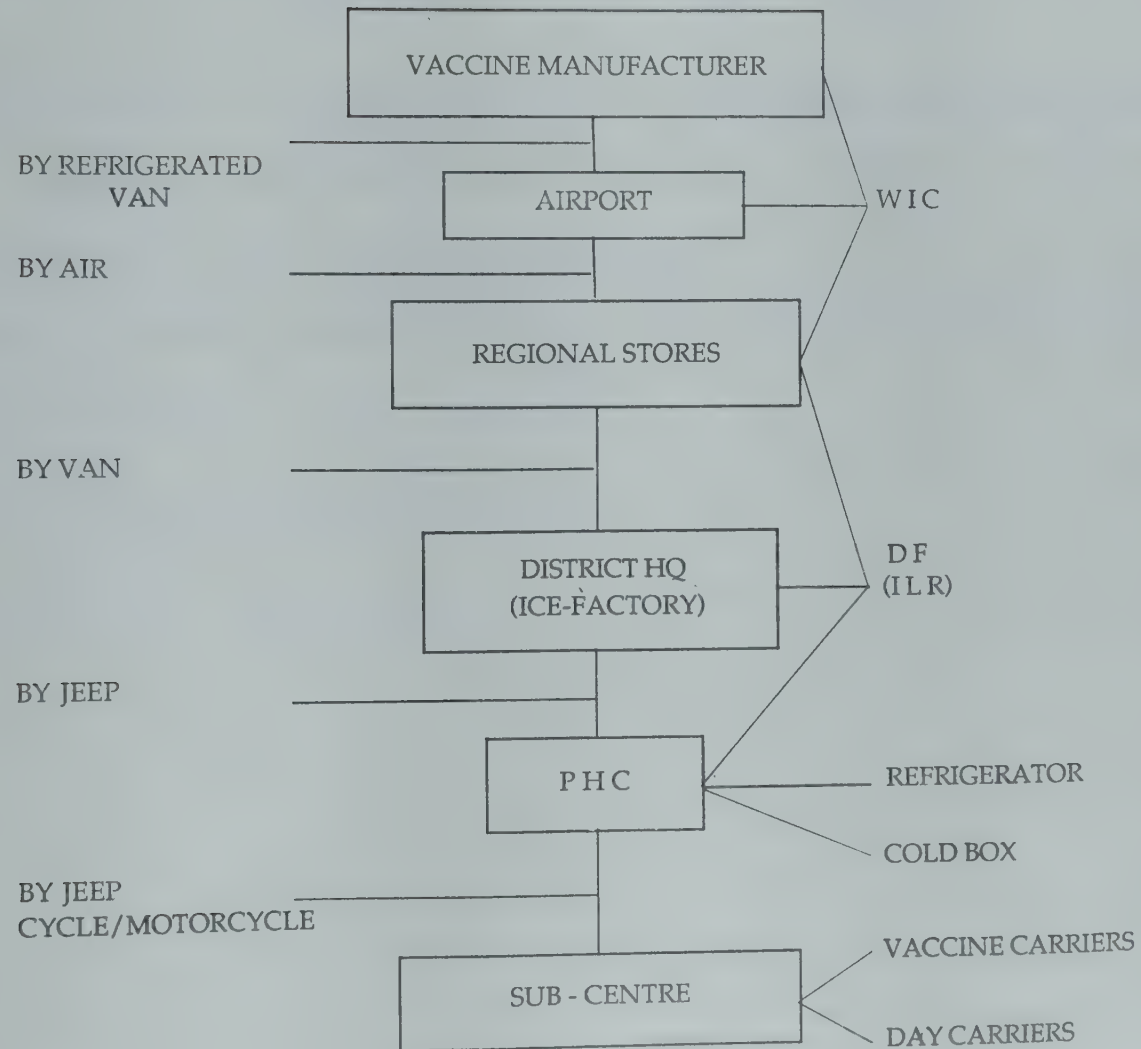
PRODUCTION OF T.T. VACCINE (In lakh doses)

S.No.	Institute	Installed Capacity	Produced			Proposed to be produced	
			1984-85	85-86	86-87	1987-88	88-89
1.	CRI, Kasauli	240.00	245.51	208.62	186.71	220.0	220.00
2.	HBPCL, Bombay	100.00	70.00	70.00	80.00	90.00	120.00
3.	P.I.I., Coonoor	80.00	54.00	61.00	71.00	80.00	90.00
4.	Hyderabad	25.00	3.06	4.50	8.19	20.00	25.00
5.	Serum Instt. Pune	--	51.79	65.17	60.08	1000.00	1000.00
6.	State Vaccine Instt., Patwadanagar, Nainital	10.00	3.20	8.00	8.69	10.00	10.00
Total:		455.00	427.56	417.29	414.67	1420.00	1465.00

VII. COLD CHAIN

COLD CHAIN

FLOW CHART



STEPS TO BE TAKEN FOR INDIGENOUS PRODUCTION OF COLD CHAIN EQUIPMENT AND STRENGTHENING OF MAINTENANCE SYSTEM

- * Develop cold chain specifications required as per vaccine storage capacity
- * Refrigeration manufacturers to develop prototype on the basis of specifications equipment
- * Refrigeration companies to be involved in maintenance of cold chain
- * Develop State infrastructure for cold chain repair and maintenance wherever feasible

MONITORING OF COLD CHAIN - FOR VACCINES MANUFACTURED IN PUBLIC SECTOR UNDERTAKING IN INDIA

- * System for recording temperature at various points of time in transit from the manufacturer to state headquarters
- * System for monitoring cold chain to be devised at the state level
- * Government of India will monitor cold chain upto state level
- * State Government will monitor maintenance of proper cold chain from the state headquarters to the PHC level
- * Vaccine procured from private sector through DGS&D
- * The supplier will give information in prescribed proforma for temperatures at various points of time during transit from the distribution point to state headquarters
- * Beyond the state headquarters the cold chain monitoring will be done by state government

VIII. RESOURCES

RESOURCES

Financial Outlay

Yearwise Estimated Expenditure

(Rupees in million)

	1985-86	1986-87	1987-88	1988-89	1989-90	Total
Non-Recurring	55	89	101	142	148	535
Recurring	185	238	304	390	486	1603
Towards vaccine production	--	--	--	--	--	262
Total	240	327	405	532	634	2400

(Say Rs. 240.00 Crores)

POSITIONING OF STAFF

Staff	Required by 1990	Appointed/* Trained
Multipurpose Worker (Female)	1,30,000	1,07,593
Multipurpose Worker (Male)	1,30,000	84,993
Female Health Assistant	21,666	17,272
Male Health Assistant	21,666	24,735
Dais	5,80,000	5,58,919
Village Health Guide	5,00,000	3,93,233
Anganwadi Workers	--	1,27,752

* Position as on 30.9.1987

**STAFFING PATTERN UNDER UNIVERSAL IMMUNIZATION PROGRAMME
AT STATE & DISTRICTS LEVEL**

Sl. No. State Level Post (One each)

1. Officer-in-Charge Cold Chain
2. Technical Assistant

District Level Post (One each)

1. District Immunization Officer *
2. Statistical Investigator
3. Refrigeration Mechanic
4. Typist
5. Driver **

* *The Post was sanctioned in 1986-87*

** *Per number of vehicles allotted to each district.*

**IX. COLLABORATING AGENCIES AND
COMMUNITY PARTICIPATION**

COLLABORATION INSTITUTES/ORGANISATIONS

Tasks Identified

- | | |
|---|------------|
| * (A) Council of Scientific & Industrial Research | Cold Chain |
| * (B) Indian Institute of Technology, New Delhi | |
| * (C) Confederation of Engineering Industry | |
-
- * Indian Council of Medical Research - Medical Research for Improvement of Services
 - * Department of Biotechnology - Indigenisation of vaccine production, and new vaccines
 - * M/s Voltas - Installation, transportation, maintenance of cold chain
 - * All India Institute of Medical Sciences (ICDS Cell) - Training, monitoring and Evaluation
 - * National Institute of Communicable Diseases - Middle level training
 - * Operational Research Group and other Institutions - Logistics

COMMUNITY PARTICIPATION

Increased community participation by Method and Group-based approaches (requires consideration at both levels, community and individual)

(i) Method adopted:

- Mass Media
- Inter-personal efforts
- Inter-personal communication

(ii) Group-based approach:

- Health Workers and ICDS Workers
- Political and Social Leaders
- Primary School Teachers and personnel of other Government Welfare Departments
- Medical Students and Medical professionals
- Organised and Co-operative Sectors

ACTIVITIES FOR MASS MEDIA

- * Designing printing and distribution of seven posters on EPI diseases
- * Preparation and distribution a folder on immunization
- * Other activities
 - (A) Video cassettes on recommendation of diseases
 - (B) Seven TV spots in Hindi on EPI diseases
 - (C) Thirteen radio spots on EPI one in Hindi and 12 in regional languages
 - (D) Radio programmes for school children
 - (E) Puppet shows in immunization in the areas of Delhi, U.P., Rajasthan and Madhya Pradesh
(Special Requests)
- * Children Story books on EPI

INVOLVEMENT OF VOLUNTARY AGENCIES

- Identify voluntary agencies in each district
- To select such agencies which can help in demand generation, enumeration and actual vaccination
- Identify major voluntary agencies spared over across the country/states/number of districts
- Identify suitable agencies to work in urban slums
- Provide financial assistance wherever unavoidable

MAJOR VOLUNTARY ORGANISATION/AGENCIES INVOLVED

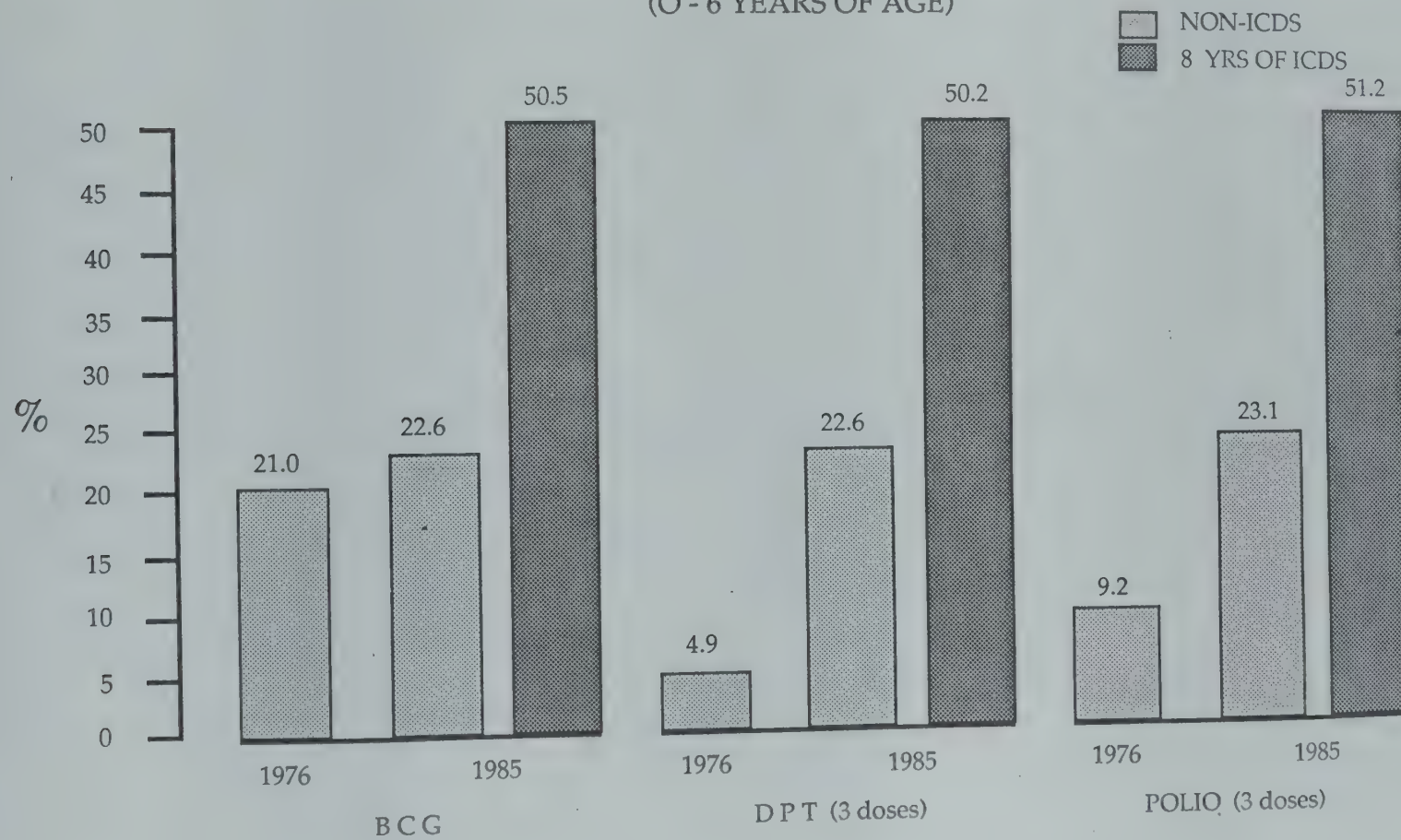
- * Rotary International
- * Indian Medical Association and its branches
- * Impact India
- * All India Women's Conference
- * Parivar Sanstha Kendra
- * Family Planning Association of India

**I.C.D.S. PACKAGE OF SERVICES IS A BIG
SUPPORT TO IMMUNIZATION PROGRAMME**

- * Immunisation, Primary Health Care, Nutrition
Intervention, - non-formal education.

PERFORMANCE OF IMMUNISATION IN ICDS AND NON - ICDS AREAS

(O - 6 YEARS OF AGE)



X. MONITORING, EVALUATION AND SURVEILLANCE

MONITORING OF THE IMMUNIZATION PROGRAMME

- | | | | |
|---|---|---|---|
| * | Monthly Performance Reports | - | States/Ministry of Health
and Family Welfare |
| * | Field Visits | - | States/Ministry of Health
and Family Welfare |
| * | Vaccination Coverage Assessment Surveys | - | States/Ministry of Health
and Family Welfare |

EVALUATION

- I. Concurrent Evaluation - Internal
- II. Evaluation by Independent Body

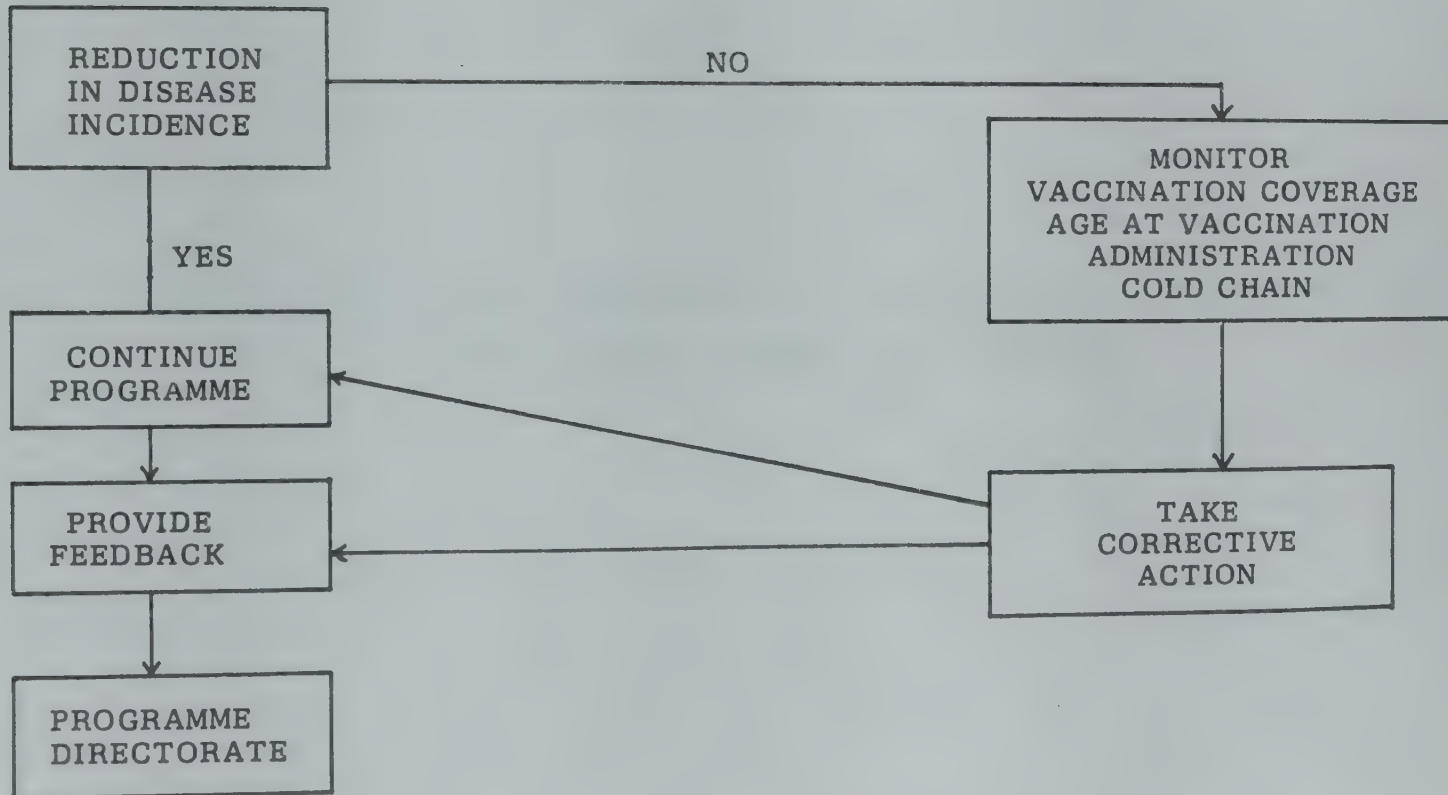
Concurrent Evaluation

- * Identify the Institute/Body which will take of this evaluation
- * Formation of core group for evaluation
- * Determination of sample
- * Distribution of proforma and collection of information, compilation and tabulation
- * Analysis

SURVEILLANCE

- I. Sentinel Surveillance - Medical Centres/AIIMS

SURVEILLANCE



XI. PROBLEMS, TECHNOLOGICAL INPUTS AND FACTORS AFFECTING IMMUNIZATION

TASKS COMPLETED

Year-wise selection of districts completed.

Requirement of vaccines year-wise assessed.

Indigenous supplies arranged.

Foreign supplies tied up.

Requirement of cold chain equipment worked out. Cold chain supplies arranged till 1987-88.

Supplies of other equipment worked out. Supplies arranged till 1987-88.

Staff sanctions upto 1987-88 issued.

Training upto 1986-87 completed.

Statutory testing of vaccine organised.

ON-GOING TASKS

- * Field Infrastructure
- * Installation and Maintenance of Cold Chain Equipment
- * Smooth Flow of Vaccine
- * Positioning of Staff
- * Training
- * Detailed Monitoring
- * Quality Control
- * Management Information
- * Urban Area Coverage
- * Health Information

PROBLEMS IN THE FIELD

- * Insufficient Motivation
- * Inadequate Health Infrastructure
- * Irregular Flow of Funds
- * Poor Logistic Support
- * Frequent Transfer of Key Personnel
- * Weak Supervision and Monitoring
- * Deficiencies in Training
- * Clashing Priority of Various Programmes
- * Low Literacy Rates
- * Inadequate Technological Inputs

TECHNOLOGICAL INPUTS BEING MOBILIZED

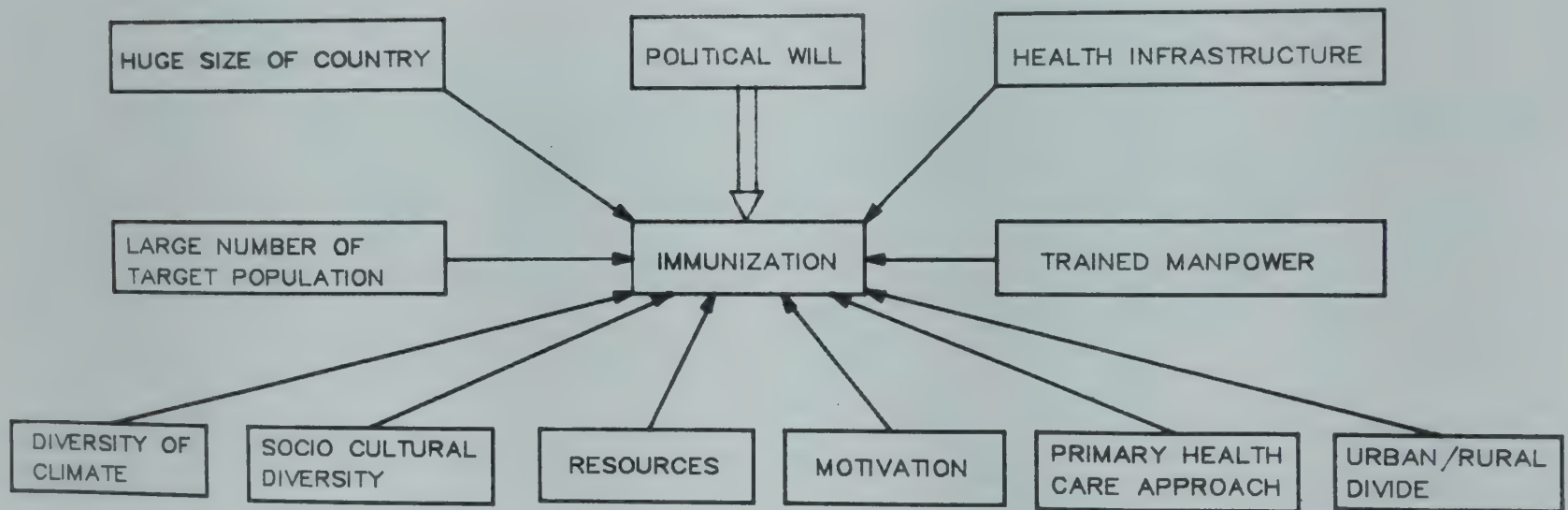
- * Cold Chain - Maintenance - Repair - Adaptation - Innovations - Indigenisation - Alternate options
- * Simulation studies for better, logistics and supplies management
- * Field testing of vaccines
- * Alternate forms of delivery of vaccination
- * Technological innovations - Colour coding - Vial packing - Electronic devices etc. (DDE, Science Advisory Group)
- * Improvements of existing vaccines to reduce drop-out rates
- * Management information system at PHC level upward

INDIA

IMMUNIZATION DROP OUT RATE



FACTORS INFLUENCING IMMUNIZATION



XII. MINI MISSION III

R&D FOR NEW AND IMPROVED
VACCINES

MINI MISSION IV

PRODUCTION OF VACCINES

MINI MISSION III

R&D FOR NEW AND IMPROVED VACCINES

OBJECTIVES

- To set up, promote, undertake and monitor highly competitive R&D activities in vaccinology with a view to develop new process technologies for new or improved vaccines and vaccine cocktails such as:
- R&D, prototype development and field evaluation of oral vaccines against cholera, typhoid, etc.
- Development of stable and environmentally safe vaccine baits for canine rabies control in India.
- Epidemiological and etiological studies as well as vaccine development and validation against hepatitis NANB and streptococcal pneumonia.
- R&D and evaluation of new sub-unit vaccines such R-DNA based and synthetic vaccines.
- Development of polyvalent vaccines and vaccine 'cocktails'.

SELECTED DISEASES FOR VACCINE R&D

- a) Urban rabies with special reference to oral vaccine baits for canine rabies control.
- b) Diarrhoeal diseases: Cholera, Shigellosis, Rotaviral diarrhoea, Salmonellosis.
- c) Typhoid
- d) Hepatitis-B
- e) Hepatitis-NANB
- f) Malaria and
- g) Pneumonia

HEPATITIS: PROJECTS AND INSTITUTIONS IDENTIFIED

- * Study of the duration & safety of genetically engineered yeast vaccine as compared to plasma derived vaccine.
 - All India Institute of Medical Sciences, New Delhi.
 - National Institute of Virology, Pune.
- * Development of new recombinant vaccines for immunization against viral hepatitis-B, rabies and malaria.
 - National Institute of Immunology, New Delhi.
- * Identification and characterisation of virus particle/particles causing NANB hepatitis - detection of humoral-immune responses, and development of reagents and tests for specific diagnosis of NANB hepatitis.
 - All India Institute of Medical Sciences, New Delhi
 - National Institute of Virology, Pune.

RABIES - PROJECTS AND INSTITUTIONS IDENTIFIED

- * Development of mass immunizing agents against canine rabies in India - urban and rural.
- * Analytical typing and survey of street virus prevalence in India.
- * Studies on the substitution of the reactogenic equine hyperimmune serum with other safer agents (interferon inducers)

Pasteur Institute, Coonoor.

National Institute of Virology, Pune.

DIARRHOEAL DISEASES: PROJECTS AND INSTITUTIONS IDENTIFIED

- * Study of rota viral infection and development of vaccines against rota viral diarrhoea.
National Institute of Cholera and Enteric Diseases, Calcutta.
Director General of Health Services, Manipur.
- * Development of improved cholera vaccine (adhesive factor)
Central Drug Research Institute, Lucknow.
Jawaharlal Nehru University, New Delhi.
- * Research and Development of diagnostics and vaccine against diarrhoeogenic E. coli.
National Institute of Cholera and Enteric Diseases, Calcutta
- * Improved diagnostic facilities for diarrhoeal diseases through DNA probes.
National Institute of Cholera and Enteric Diseases, Calcutta.
Benaras Hindu University, Varanasi

(contd...)

DIARRHOEAL DISEASES (contd...)

- * Development of new vaccines against *S. typhi*.
All India Institute of Medical Sciences, New Delhi.
- * Studies on the development of attenuated cholera vaccine.
Benaras Hindu University, Varanasi.
- * Studies on development of an effective vaccine against shigellosis caused by *Shigella dysenteriae*.
National Institute of Cholera and Enteric Diseases, Calcutta.

PERTUSSIS AND OTHERS

- * R&D cum production, standardisation and quality control of a cellular pertussis vaccine in India.
Central Research Institute, Kasauli.
Pasteur Institute, Coonoor.
- * Development of an evaluation unit at AIIMS for vaccines used in children.
All India Institute of Medical Sciences, New Delhi.

MINI MISSION IV

PRODUCTION OF VACCINES

OBJECTIVES

- Modernisation and capacity expansion in major public sector units to meet the EPI demands for DPT, DT, TT, BCG and Typhoid vaccines.
- To establish indigenous production capacities before 1990 for Measles, Polio and tissue culture Rabies vaccine employing advanced technologies.
- To undertake detailed evaluation including field trials of R-DNA hepatitis-B vaccine and new pertussis vaccine and to set up indigenous production capacities for those vaccines by 1990 or soon thereafter.

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SOME DESIRABLE CHARACTERISTICS OF VACCINES CONSIDERED IN THE CHOICE OF VACCINES/PROCESS TECHNOLOGIES

High efficacy

(Minimum number of doses to ensure long lasting immunity, better sero-conversion etc.)

Safety and minimum side effects.

Long shelf life.

Heat stability.

Distribution through common cold chain.

Ease of application.

Adequate availability.

Ability to combine with other vaccines as vaccine 'Cocktails', and

Low cost.

DROP-OUT AND VACCINATION COVERAGE

Doses/ Visits	Drop-out Rate (Percent)	Number of recipients	
		First Visit	Last Visit
3	25	100	56.25
3	20	100	64.00
3	10	100	81.00
3	7.5	100	85.50
4	5	100	85.70

Minimum vaccination visits during first year — 4

Note: The drop-out rate in India is about 25%. Vaccines requiring multiple doses calls for multiple visits/recalls, which results in a large cumulative drop-out and low coverage. Vaccines requiring fewer doses (ideally single shots) would greatly help improve the coverage.

SOME SALIENT FEATURES OF VACCINE PRODUCTION STRATEGY

- Number of doses manufactured and schedule of production and supply to match the estimated annual requirements of the EPI.
- Quality of the products to meet strictly the standards set by the World Health Organisation.
- Quality of the products to be certified by an independent National Quality Control and Standardization Laboratory.
- The cost of indigenously produced vaccine to be internationally competitive and to enhance the cost-effectiveness of the national programme.
- The production units should have strong in-house R&D component.

PRODUCTION OF VACCINE — INDUSTRIAL PROJECT

Stage-I

-	Live attenuated measles vaccine	25 Million doses
-	Oral Polio vaccine	100 Million doses
-	Killed polio vaccine	50 Million doses
-	Tissue culture rabies vaccine	5 Million doses

Stage-II

-	R-DNA Hepatitis-B Vaccine	2 Million doses
-	Acellular pertussis vaccine	50-80 Million doses

TECHNOLOGIES FOR PRODUCTION OF VACCINES

Measles Vaccine

- I. Chick Embryo Fibroblast Technology
- II. Human Diploid Cell-Based Cell Cultures

Oral Polio Vaccine

Primary Monkey Kidney Cell Cultures

Killed Polio Vaccine

&

Rabies Vaccine

Continuous Vero Cell Microcarrier Fermentation Technology

Hepatitis-B Vaccine

R-DNA based Yeast/CHO Cell Technology

New Pertussis Vaccine

- Mono Component-Toxoid Vaccine (Sub-unit Vaccine)
- Or Two Component-Toxoid and Filamentous Haemagglutinin Vaccine (Sub-unit Vaccine)

CAPACITY EXPANSION IN EXISTING UNITS

Vaccine	Institute	Production 85-86	Planned Capacity 89-90	Percent Expansion
DPT	CRI, Kasauli	13	20	54
	PII, Coonoor	9	15	67
	HBPCL, Bombay	6	10	67
	Total	28	45	61
Tetanus Toxoid	CRI, Kasauli	22	22	--
	PI, Coonoor	6	10	67
	HBPCL, Bombay	8	14	75
	Total	36	46	21
BCG	BCG Vaccine Laboratory, Madras	16	22	27

EXPECTED DATES OF BULK INDIGENOUS PRODUCTION OF VACCINES

Measles Vaccine	- April 1989
Polio Vaccine	- January 1990
Rabies Vaccine	- January 1990
Hepatitis-B Vaccine	- December 1990 or soon thereafter.
New Pertussis Vaccine	- December 1990 or soon thereafter.

PROGRESS MADE

- Two technical expert committees studied the vaccine requirements, state of the art of technologies for vaccine production and recommended urgent steps to set up indigenous R&D production facilities through transfer of most advanced and appropriate technologies for:
 - Hyper attenuated measles vaccine
 - Injectable polio vaccine (Vero)
 - Inactivated tissue culture rabies vaccine &
 - R-DNA Hepatitis-B vaccine.
- An inter-ministerial negotiating committee finalised the technologies and terms and conditions of transfer of technologies for measles, rabies and polio vaccines.
- Evaluation of technologies for hepatitis-B vaccines, oral polio vaccine and new pertussis vaccines are in progress.

